Remarks

Claims 1-12, 14-16, 18-20, 24, 25, and 31-49 are pending in the present application. The present invention is directed to a homogeneous, thermoreversible gel film comprising a film forming amount of kappa-2 carrageenan, and optionally at least one of a plasticizer, a second film former, a bulking agent, and a pH controlling agent; wherein said film:

(i) further comprises sodium cation,

(ii) has a solids content of at least 50% based on all components in the gel film, and

(iii) has a break force strength of at least 1,500 grams.

The present invention is also directed to soft capsules and solid forms comprising the foregoing gel film.

As detailed below, kappa-2 carrageenan was known to have a different chemical structure and different physical properties than kappa carrageenan, iota carrageenan and physical mixtures thereof. In particular, as noted in the present specification, as well as set forth in the art cited by the Applicants and the Examiner, kappa-2 carrageenan was considered to be weakly gelling. To Applicants' surprise, the gels of the present invention comprising kappa-2 carrageenan have been found to form surprisingly strong gel films that are suitable, for example, in the manufacture of soft capsules, and to possess unexpected processing advantages.

Interview

An interview was conducted on September 24, 2009 ("Interview"), in regard to the above identified application between Examiners Helm and Woodward and the Undersigned. The Undersigned notes with thanks and appreciation the courteous manner by which the Interview was conducted. The substance of the Interview is described in a paper issued by Examiners Helm and Woodward on September 29, 2009.

35 USC § 103

At pages 3-9 of the Office Action, the Examiner rejected: (i) claims 1-11, 14-16, 18-20, 24-25, 34-39, 42 and 44-49 under 35 USC § 103 as being unpatentable over Gilleland in view of de Vries and van de Velde; (ii) claims 1, 38-40, and 42-44 under 35 USC § 103 as being unpatentable over Gilleland in view of de Vries and van de Velde as applied to claims 1-11, 14-16, 18-20, 24-25, 34-39, 42 and 44-49 and further in view of Parikh; and (iii) claims 1, 12 and 31-33 under 35 USC § 103 as being unpatentable over Fonkwe in view of de Vries and van de Velde. The Examiner's position may be summarized as follows.

The Examiner cites Gilleland for teaching that kappa and iota carrageenans provide good performance in gel film applications. The Examiner acknowledges that Gilleland does not teach the specific use of kappa-2 carrageenan in such applications, but relies on the secondary references to cure this deficiency. The Examiner cites Fonkwe as teaching a gel film, soft capsules and solid dosage forms comprising iota carrageenan, kappa carrageenan, plasticizer and bulking agent. The Examiner acknowledges that Fonkwe does not disclose the use of kappa-2 carrageenan, but relies on the secondary references to cure this deficiency. The Examiner cites de Vries as teaching kappa-2 carrageenan having properties that are intermediate to both kappa and iota carrageenan (citing Table 1 in de Vries) and further acknowledges that de Vries does not teach the presence of sodium cations (see the Office Action at page 11, first full paragraph). The Examiner cites van de Velde as teaching kappa-2 carrageenan containing sodium cations and for teaching that iota and kappa carrageenans act independently of one another and gel at different temperatures. The Examiner argues that van de Velde suggests that kappa-2 carrageenan would have the added benefit of conferring properties intermediate to both kappa and iota carrageenans without the two physically

separating and acting independently. Therefore, the Examiner concludes that one skilled in the art would have found it obvious to combine the teachings of Gilleland and Fonkwe with the teachings of de Vries and van de Velde to arrive at the presently claimed invention.

Applicants respectfully traverse the foregoing rejections on the basis that the cited prior art, alone or in any combination, does not disclose or suggest: (i) the gel films of the present invention comprising kappa-2 carrageenans, sodium cation, solids content and break force strength; or (ii) soft capsules and solid forms comprising such gel films. In addition, a Declaration is submitted herewith that demonstrates the unexpected processing advantages of the present invention against the closest cited prior art (the tests outlined in the Declaration were those discussed during the Interview).

Applicants have traversed the foregoing rejections in the past and have presented detailed comments in support of such traversals. For purposes of brevity, such detailed comments are incorporated herein by reference and will not be repeated in detail here. Rather, Applicants herein summarize the key points of record, as well as points discussed during the Interview, and discuss the Declaration submitted herewith.

(1) As detailed by the Applicants in the present specification, and as discussed during the Interview, kappa-2 carrageenan was known in the art to have a different chemical structure and different physical properties than kappa carrageenan, iota carrageenan or physical mixtures thereof, and was expected to be weakly gelling.

(2) Background – Applicants explained in the present specification at page 10 that iota and kappa carrageenans were known to be "gelling carrageenans" and that, in distinction, kappa-2 carrageenan was known to be "weakly gelling" and to have properties that are different than physical blends of kappa and iota carrageenan. For example, Falshaw refers to kappa-2 carrageenans having "different properties to simple mixtures of kappa and iota

carrageenan" (see Falshaw at page 442). Applicants further refer to the following reference submitted in an IDS on November 20, 2008: Marine Colloids Application Bulletin, G-39, 1990 ("Technical Bulletin"). This Technical Bulletin discusses the water gelling properties of various carrageenans. In particular, this Technical Bulletin states the following:

> "In order to consider a carrageenan for use in an aqueous gelling application, the prospective user should be familiar with the basic types of carrageenan that are available, their properties and how to use them in the system...The two basic water gelling carrageenans are kappa and iota...The kappa-2 carrageenan has properties intermediate between kappa and iota, however, it produces rather soft gels, therefore it is not often used by itself for preparation of water gels."

See pages 2 and 6 of the Technical Bulletin (emphasis added).

This Technical Bulletin does not list kappa-2 carrageenan as a known water gelling carrageenan and, further, states that because it is known to produce soft gels, "it is not often used by itself for preparation of water gels." This is consistent with the other references already submitted by the Applicants on this point.

(3) The Primary References - The Examiner admits that the primary references do not disclose films comprising kappa-2 carrageenan, but argues that one skilled in the art would have been motivated to modify the teachings therein and use a different carrageenan (such as kappa-2 carrageenan) based on de Vries and van de Velde. However, the primary references disclose the use of the specific carrageenans developed therein as being critical and, as such, it is not seen why one skilled in the art would be motivated to use a different carrageenan altogether. For example, Gilleland teaches:

A. Film compositions made from iota carrageenan had a slow film formation rate and were soft, weak, and very elastic (see Example 10);

B. Tests were also performed on kappa carrageenan compositions and resulted in films that would have manufacturing problems (see Example 10);

C. Tests were then performed on physical blends of kappa and iota carrageenan and such were found to have stronger films than either kappa or iota alone (see Example 10); and

D. "Carrageenan gels by coiling portions of its carbohydrate backbone into helixes with portions of another carrageenan molecule. If the gel is composed of helixes containing one strand of kappa carrageenan and one strand of iota carrageenan, predicting the softening temperature is not straightforward" (see Example 10; emphasis added).

As a result, it is respectfully submitted that one skilled in the art would not have found motivation to modify the teachings of Gilleland as suggested by the Examiner since Gilleland teaches the criticality of using physical blends of kappa and iota carrageenan.

Moreover, Fonkwe teaches the following:

A. "There are five distinct types of carrageenan, each of which behaves differently and has distinct properties. The types of carrageenan are iota, kappa, lambda, mu and nu carrageenan. These types of carrageenan can significantly vary in properties" (see col. 1, lines 55-59 (emphasis added)). Kappa-2 carrageenan isn't even mentioned as one of the carrageenan types.

B. "Both kappa and iota carrageenan, the predominant carrageenan types, are able to form gels" (see col. 1, lines 61-63). There is no mention of kappa-2 carrageenan as a gelling carrageenan.

C. "The type of carrageenan used affects the physical properties of the final gel or film" (see col. 2, lines 7-8).

As a result, as is the case with Gilleland, it is respectfully submitted that one skilled in the art would not have found motivation to modify the teachings of Fonkwe as suggested by the Examiner since Fonkwe also teaches the criticality of using the physical blends of iota and kappa carrageenan referred to therein.

(4) de Vries – The Examiner cites de Vries as teaching kappa-2 carrageenan having properties that are intermediate to both kappa and iota carrageenan (citing Table 1 in de Vries) and argues that the reference suggests the use of kappa-2 carrageenan in the present invention. However, as noted previously, de Vries, at Table 1, states that the metals "required for gelling" hybrids are both calcium and potassium. There is no disclosure or suggestion in de Vries of the gelling capability of a kappa-2 gel film containing sodium as in the present invention (the Examiner relies on van de Velde for this teaching, but van de Velde does not teach kappa-2 carrageenan as being strongly gelling as noted below). Moreover, Applicants clarify and explain that: (i) Table 1 in de Vries refers generally to "hybrids," but it is not believed that one skilled in the field would read Table 1 to specifically refer to kappa-2 carrageenan hybrids in water gels given the knowledge in the field that kappa-2 carrageenan was known to be weakly gelling; and (ii) to the extent Table 1 is construed by those skilled in the field to refer to gelling capabilities in dairy systems, one skilled in the field would not interpret any such teachings to suggest the gelling capability in non-dairy systems since gelation in a dairy system is very different (i.e., due to the presence of milk proteins) than gelation in non-dairy systems.

(5) van de Velde – Contrary to the Examiner's position, the teachings in this reference actually support the patentability of the present invention and are inconsistent with the manner in which the Examiner reads de Vries. That is, the reference states:

A. "The rheological properties of the gelling carrageenans (k and i) are quite distinct: the k-type forms gels that are hard, strong and brittle, whereas i-carrageenan forms soft and weak gels." See van de Velde at page 272, second column, lines 4-8 from the bottom.

B. "The gelation on cooling of k- or i-carrageenan solutions is generally accepted to proceed in two steps. The first step is the coil-to-helix transition from a disordered (random coil) to an ordered (helical) conformation…The gelation of the helical polymers (second step) can proceed on either a helical or superhelical level." See van de Velde at pages 278 and 279.

C. "The k/i-hybrid did not show a clear coil-to-helix transition…or any sudden change in the increase in viscosity with decreasing temperature….Chains that are composed of both k- and i- repeating units are expected to contain kinking sequences (k-units adjacent to i-units) that prevent a regular helix formation." See van de Velde at page 279, second column, first and second paragraphs (emphasis added).

As a result, van de Velde actually teaches that kappa-2 carrageenan would not be expected to be useful in the gel films, soft capsules and solid forms of the present invention. The teachings in van de Velde are consistent with the knowledge in the field that kappa-2 carrageenan was not known to be a gelling carrageenan. Moreover, it is respectfully submitted that the Examiner's reading of de Vries (as suggesting that kappa-2 carrageenan would be known to form strong gels as in the present invention) is inconsistent with van de Velde (which teaches that kappa-2 carrageenan was known to be weakly gelling).

(6) Painter – The Examiner relies on Painter for the proposition that it is well known in polymers that polymer blends and copolymers are utilized to produce a preparation

"that has properties that are intermediate to the two homopolymers" (see the Office Action at page 17). However, a review of Painter does not support this statement. Rather, Painter more fully discloses that copolymers are often synthesized "in an attempt to obtain properties that are intermediate, superior or just different from those of the homopolymers" (see Painter at page 15; emphasis added).

(7) Applicants respectfully submit that the Examiner has not established a proper *prima facie* case of obviousness for the foregoing reasons. However, assuming that the Examiner has established a proper *prima facie* case, Applicants submit herewith a Declaration for the Examiner's consideration.

A. As discussed above, Fonkwe discloses a film forming composition comprising iota and kappa carrageenan. Gilleland teaches that a combination of kappa carrageenan and iota carrageenan, most preferably in a weight ratio of 1:1, is "especially preferred" (see col. 2, lines 14-16). Example 10 of Gilleland tested the flow properties against temperature (see also Figure 2) of kappa carrageenan and the 1:1 mixture of kappa carrageenan and iota carrageenan as a measure of the processing advantages thereof, and Gilleland teaches in Example 10 that the physical mixture (1:1) of kappa and iota carrageenan was found to be preferred. In view of these teachings, similar tests were conducted as outlined in the Declaration to quantitatively measure the flow properties at various temperatures of the present invention as compared to a physical 1:1 mixture of kappa carrageenan and iota carrageenan. This work was intended to compare the flow rates of the two tested compositions differing only in the selection of the carrageenan.

B. The tests that were performed (as set forth in the Declaration) are the tests that were discussed with the Examiners during the Interview (i.e., comparing flow rate against temperature).

C. The tests determined that the two compositions:

> "behaved significantly differently at similar test conditions. The substitution of kappa-2 carrageenan for an equal amount of a physical mixture of kappa and iota carrageenan in similarly prepared and concentrated compositions did not result in samples with similar flow ratings at lower oven storage temperatures. The kappa-2 carrageenan sample of the present invention throughout the tested temperature range had a high flow rating (indicating a readily flowing material), whereas the sample containing the physical mixture decreased in flow at the lower temperatures to a point of no flow at the lowest tested temperature."

See the Declaration at Paragraph III.A and Figure 1 therein.

D. Moreover, the tests determined that the "sampled material that remained on the flow apparatus after testing and cooling were physically different. The samples that were made with kappa-2 carrageenan remained soft and malleable whereas those made with the physical mixture of kappa and iota carrageenan became rigid enough to be removed from the apparatus in one piece." See the Declaration at Paragraph III.B.

E. Thus, it is respectfully submitted that the testing in the Declaration demonstrates the unexpected flow and processing advantages of the kappa-2 films of the present invention when compared against the closest prior art.

In view of the foregoing comments and the testing set forth in the attached Declaration, it is respectfully submitted that the present invention is unobvious and patentable over the cited prior art. Accordingly, withdrawal of the foregoing rejections is respectfully requested.

35 USC § 103

At page 9 of the Office Action, the Examiner rejected claims 1 and 41 under 35 USC § 103 as being unpatentable over Augello in view of de Vries and van de Velde. The Examiner's position is that Augello teaches a gel film composition comprising microcrystalline cellulose and carrageenan. The Examiner acknowledges that Augello does

not disclose the use of kappa-2 carrageenan, but again relies on the teachings of de Vries and van de Velde to conclude that it would have been obvious to one skilled in the art to use kappa-2 carrageenan in the gel film composition of the present invention.

Applicants respectfully traverse the foregoing rejection and request reconsideration thereof.

That is, Augello is directed to an edible coating composition comprising microcrystalline cellulose, carrageenan and either a strengthening polymer, plasticizer or both. Augello discloses the use of kappa carrageenan, iota carrageenan or lambda carrageenan. As the Examiner acknowledged, Augello fails to disclose the use of kappa-2 carrageenan therein. As a result, the Examiner again turns to de Vries and van de Velde.

For the reasons set forth above, none of de Vries or van de Velde disclose and/or suggest that kappa-2 carrageenan can be used in the gel films, soft capsules and solid forms of the present invention.

Furthermore, nothing in the cited art suggests the flow and processing advantages of the present invention as set forth in the Declaration submitted herewith.

In view of the foregoing, it is respectfully submitted that the cited prior art, alone or in any combination, does not disclose or suggest the presently claimed invention. Accordingly, withdrawal of the foregoing rejection is respectfully requested.

Obviousness-Type Double Patenting Rejection (Provisional)

At pages 11-16 of the Office Action, the Examiner issued numerous provisional obviousness-type double patenting rejections. Applicants request that these rejections be held until such time as a notice of patentable subject matter has been received in the applications. An appropriate terminal disclaimer may be filed at that time, if necessary.

Applicants respectfully submit that the presently claimed invention is in condition for allowance. Early, favorable action is earnestly solicited.

Respectfully submitted,

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November 16, 2009

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Attachment: Declaration Under 37 § CFR 1.132

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